good storage and distribution practice, shall be disregarded.

(4) With respect to a master lot of insulin, 5 years after date of issue if the master lot is a solution, or 10 years after date of issue if the master lot is a solid.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40286, Nov. 15, 1974]

§429.47 Authority to refuse certification service.

When the Commissioner finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by §429.60; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section;

the Commissioner may immediately suspend service to such person under the regulations in this part, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

Subpart F—Administrative Procedures

§429.50 Hearing procedure.

Hearings pursuant to §429.47 shall be governed by part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15674, Mar. 22, 1977]

§429.55 Fees.

(a)(1) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(2) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged.

(b) The fees for requests for certification submitted under §429.40 are as follows:

(1) $2,400 for each master lot or mixture of two or more master lots or parts thereof.

(2) $1,700 for each dosage form batch.

(3) The fees established in this paragraph may increase as Federal salary costs increase. The rate of increase will be no higher than Federal salary increases, commencing with pay raises on or after January 1, 1997. Notification of the exact fees established and adjustments will be communicated directly to the manufacturers of insulin products.

(c) A person requiring continuing certification services may maintain an advance deposit of the estimated costs of such services for a period of 2 months or more. Such deposits shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in these regulations unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(d) The unearned portion of any advance deposit made pursuant to paragraph (b) or (c) of this section shall be refunded to the depositor upon his application.

(e) All advance deposits required by the regulations in this part 429 shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All deposits shall be forwarded to the Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204, whereupon after making appropriate record thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United

States, for deposit to the special account ''Salaries and Expenses, Certification, Inspection and Other Services, Food and Drug Administration.''

[39 FR 11750, Mar. 29, 1974, as amended at 42 FR 27227, May 27, 1977; 48 FR 788, Jan. 7, 1983; 60 FR 56516, Nov. 9, 1995]

Subpart G—Records

§ 429.60 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 2 years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

PART 430—ANTIBIOTIC DRUGS; GENERAL

Subpart A—General Provisions

Sec.

430.3 Definitions applicable to all certifiable antibiotic drugs.
430.4 Definitions of antibiotic substances.
430.5 Definitions of master and working standards.
430.6 Definitions of the terms ''unit'' and ''microgram'' as applied to antibiotic substances.

Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 357, 371; 42 U.S.C. 216, 241, 262.

Subpart A—General Provisions

§ 430.3 Definitions applicable to all certifiable antibiotic drugs.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this chapter covering the certification of antibiotic and antibiotic-containing drugs.

(b) The term *Commissioner* means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purpose of the regulations for the certification of antibiotic and antibiotic-containing drugs.

(c) The term *act* means the Federal Food, Drug, and Cosmetic Act and amendments thereto. (52 Stat. 1040 *et seq.*; 21 U.S.C. 301–392).

(d) The term *U.S.P.* means the official Pharmacopeia of the United States, including supplements thereto. The term *N.F.* means the official National Formulary, including supplements thereto.

(e) The term *batch* means a specific homogeneous quantity of a drug.

(f) The term *batch mark* means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(g) The term *manufacture* does not include the use of a drug as an ingredient in compounding any prescription issued by a practitioner licensed by law to administer such drug.

[39 FR 18925, May 30, 1974]

§ 430.4 Definitions of antibiotic substances.

(a) The following are definitions of antibiotic substances:

(1) *Penicillin.* Each of the several antibiotic substances (e.g., penicillin F, penicillin G, penicillin X) produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum,* and each of